VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Local Anaesthesia (Insensitivity to pain)

In UK, 70% of paediatric anaesthetists practised paediatric anaesthesia as more than 50% of their workload. 96% use caudal anaesthesia (a regional numbness resulting from injection of an anesthetic agent into the lower end of the spinal canal) and 72% use caudal, epidural (space outside the spinal cord) and peripheral block. 91% have no lower age limit for using caudal anaesthesia. 58% used adjuvants with local anaesthetics in caudal block, the most common being fentanyl, clonidine, diamorphine and ketamine. Each dentist in Canada injects approximately 1,800 cartridges of local anesthetic yearly, and it has been estimated that more than 300 million cartridges are administered by dentists in the United States every year.

VI.2.2 Summary of treatment benefits

Lidocaine hydrochloride is a local anesthetic and belongs to a class of drugs called amide type local anesthetics. It produces loss of feeling or sensation confined to one part of the body. Lidocaine Hydrochloride Injection may be used to produce local numbness (anesthesia)

by injection of the solution into or around the area of operation. It may also be used to produce local anesthesia by injection of the solution close to the nerves whose conduction is to be cut off, or into the epidural space near the spinal cord, or by administering the solution into a vein in a limb that has been isolated from the circulation by means of a tourniquet (bandage that stops the flow of blood from vessel by applying pressure).

Accord has not done any studies to evaluate the expected benefits of Accord's Lidocaine considering its similarity to the currently marketed/reference product.

VI.2.3 Unknowns relating to treatment benefits

Lidocaine Injection is not recommended for use in neonates. The optimum serum concentration of lidocaine required to avoid toxicity, such as convulsions and cardiac arrhythmias, in this age group is not known.

VI.2.4 Summary of safety concerns

Important identified risks:

Risk	What is known	Preventability
Toxic effect on central nervous system (CNS toxicity)	Pins and needles and dizziness are reported commonly (which may affect up to 1 in 10 people) Convulsions, numbness of the tongue or tingling sensations around the mouth, ringing in the ears or being sensitive to sound, visual disturbances, loss of consciousness, tremor, drowsiness, light-headedness, tinnitus, feeling of intoxication, difficulty in speaking are reported uncommonly (which may affect up to 1 in100 people). Changes in sensations or muscle weakness (neuropathy), inflammation of a membrane surrounding the spinal cord (arachnoiditis) which can cause pain in the lower back, or pain, numbness or weakness in the legs are rarely reported (which may affect up to 1 in 1000 people) In case of large doses, rapid onset of convulsions can be the first symptom. Restlessness, dizziness,	Yes During the treatment with lidocaine, you should inform your doctor or nurse or pharmacist if you experienced any of the mentioned nervous system events. In the event of an overdose, doctor should take immediate steps to maintain the circulation and respiration and to control convulsions. Doctor may give intravenous diazepam or thiopental sodium, to treat convulsion.

Risk	What is known	Preventability
	visual disturbances, perioral paraesthesia, nausea. Subsequently ataxia, auditory changes, euphoria, confusion, speech difficulty, paleness, sweating and tremor are reported.	
Toxic effect on heart (Cardiac toxicity)	You should not be given this medicine: If you have very low blood pressure, or if you have lost too much blood or other body fluids or your heart is unable to pump enough blood for other reasons, you should not get lidocaine injected into your spine. Slow heart beat, High blood pressure are reported commonly (which may affect up to 1 in10 people) Irregular or stopped heart beat, Slowed or stopped breathing is reported rarely (which may affect up to 1 in 1000 people).	Yes Talk to your doctor or pharmacist or nurse if you suffer from any heart problems such as slow or irregular heart beat or heart failure Talk to your doctor or pharmacist or nurse before using lidocaine if you are treated with medicines used to treat an irregular heart beat (for example, amiodarone) or heart problems.
Allergy (Use in patients with hypersensitivity to local anaesthetic of the amide type	Allergic reactions are reported to the patients who are allergic to this type of drugs (anaesthetics of the amide type)	Yes You should not take this medicine: If you are allergic to lidocaine

Risk	What is known	Preventability
or to any of the excipients)		hydrochloride, local anaesthetics of the amide type or any of the other ingredients of this medicine. During the treatment, Tell your doctor immediately if you have allergic reaction,

Important potential risks

Risk	**What is known**
Serious adverse reactions associated with local anaesthetic procedures	More serious side effects from being given too much lidocaine may follow, such as balance and coordination disorders, auditory changes, euphoria, confusion, problems with your speech, paleness, sweating, trembling, convulsions, effects on your heart and blood vessels, loss of consciousness, coma and stopping breathing for a short while (apnoea).
Ability to produce episodes of a rare inherited disease that affects the skin and nervous system (Porphyrinogenicity)	Lidocaine has been shown to cause a rare inherited disease that affects the skin and nervous system (porphyrinogenic) in animals and should be avoided in persons suffering from porphyria. Patients are advised to talk to doctor or pharmacist before using Lidocaine solution for injection if they have this disorder.
Use during the pregnancy	If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine. Paracervical block (an anesthetic procedure used in obstetrics and gynecology) can sometimes cause foetal increased/decreased heart rate, and careful monitoring of the foetal heart rate is necessary.
Damage genetic information or cause cancer (Genotoxicity/carcinogenicity of 2,6-dimethylaniline) in	Lidocaine showed no genetic damage in tests. However, a substance remain after a drug is broke down (metabolite of lidocaine, 2,6-dimethylaniline) showed evidence of genotoxic activity.

Risk	What is known
short term intermittent use	

Missing information

Risk	What is known
Nil	

VI.2.5 Summary of additional risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No studies planned.

VI.2.7 Summary of changes to the risk management plan over time

Version	Date	Safety Concerns	Comment
2.0	21 January 2015	Following risks were updated: *Important Identified Risk:* • Systemic toxicity involving CNS is changed to CNS	RMP has been updated as per day 70 comments from RMS under DCP procedure (SE/H/1430/001-002/DC)

Version	Date	Safety Concerns	Comment
		toxicity • Systemic toxicity involving CVS is changed to Cardiac toxicity • Use in patients with hypersensitivity to local anaesthetic of the amide type or to any of the excipients added *Important Potential Risk:* • Porphyrinogenicity is changed to Use in patients with acute porphyria • Foetal/neonatal Anaesthetic complication through maternal drug exposure is changed to Use during the pregnancy • Genotoxicity/carcinogenicity of 2,6-dimethylaniline in short term intermittent use added *Missing Information:* • Use in neonates is removed	